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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,314	08/05/2002	Laura M McIntosh	83815-1402	7291

7590

01/13/2005

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EXAMINER

SHAW, SHAWNA JEANNINE

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 01/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/089,314	Applicant(s) MCINTOSH ET AL. <i>CM</i>	
	Examiner Shawna J. Shaw	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 8/5/02, 9/17/02.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>09172002</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Drawings***

1. The drawings are objected to under 37 CFR 1.83(a) because they fail to show color designations as described in the brief description of Figure 3 in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Interpretation/Definitions***

2. The examiner understands from the specification that “skin disease” does not include cuts or burns (see p. 4 lines 23-25), but could encompass compositional changes such as hypoxia or dehydration (see p. 9 lines 10-30).

***Claim Objections***

3. Claim 8 is objected to because of the following informalities: In claim 8, “the diagnostic spectral wavelengths” lacks antecedent basis. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 3-7 are rejected under 35 U.S.C. 102(a) as being anticipated by Sowa et al. “Near-Infrared Spectroscopic Assessment of Tissue Hydration Following Surgery.”

Regarding claims 1 and 3-7, Sowa et al. teach identifying a skin disease (i.e, dehydration) by comparing IR spectra of skin tissue after surgery with pre-operative

(i.e., control) IR spectra at selected diagnostic wavelengths corresponding to water absorption bands. See p. 63-65.

5. Claims 1, 3-6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Haaland et al.

Regarding claims 1, 3 and 6-8, Haaland teach identifying a skin disease, such as skin cancer (col. 1 lines 59-63, col. 6 lines 10-14), by performing multivariate classification of measured/disease spectra (inherently involving comparison to a reference) at selected IR wavelengths.

6. Claims 1, 3-7, 9, 10, 12 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Costa et al. '553.

Regarding claims 1, 3-7 and 9, Costa et al. disclose identifying a skin disease, such as cancerous tissue, cervical cancer, etc., by performing multiple comparisons between visible spectra of diseased tissue and control/reference spectra corresponding to specific disease states. See claims 1, 3-6, 9, 10, 13-16, 19, 20, 22, 23 and 26-29. Further regarding claims 10, 12 and 13, Costa et al. disclose performing a biopsy to test and calibrate the sensitivity and specificity of the spectral analysis (col. 23 lines 24-37).

### ***Claim Rejections - 35 USC § 103***

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 2 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haaland et al. or Costa et al.

Regarding claims 2 and 11, although Haaland et al. and Costa et al. disclose identifying diseases such as skin cancers - dysplastic melanocytic nevi; banal nevi; lentiginies; actinic keratoses; seborrheic keratoes; basal cell carcinomas or malignant melanomas are not explicitly addressed. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to identify such skin diseases in Haaland et al. or Costa because Applicant has not disclosed that identification of any of the above diseases provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the method of identifying skin cancers of Haaland et al. or Costa et al. because they all utilize spectra in the visible/near-IR wavelength range.

***Conclusion***

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Jackson et al. (6,424,859) and Hochman (6,671,540) demonstrate that performing a diagnosis (other than skin disease) based on comparison of patient IR spectra to control data is known. See claims 1-14 of Jackson and claims 1, 16 and 23 of Hochman. Jackson et al. further demonstrates that performing multivariate analysis and region selection at oxyhemoglobin, water, lipid, etc. absorption bands is also known. See fig. 1 and 2.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawna J. Shaw whose telephone number is (571) 272-4743. The examiner can normally be reached on 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3737

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Shawna J. Shaw  
Primary Examiner  
Art Unit: 3737  
01/07/2005